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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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In re application of:
Konopitzky, *et al.*
Appl. No. 09/631,863
Filed: August 3, 2000
For: **Tumor-Associated Antigen (R11)**

Confirmation No. 8920
Art Unit: 1642
Examiner: Minh-Tam Davis
Atty. Docket: 0652.2480001/EKS/CM

14
10/2/02

Reply To Restriction Requirement

Commissioner for Patents
Washington, D.C. 20231

Sir:

In reply to the Office Action dated August 27, 2002, requesting an election of one species to prosecute in the above-referenced patent application, Applicants hereby provisionally elect to prosecute the full length species of the previously elected invention of Group I, drawn to a tumor associated antigen of SEQ ID NO:2. Claims 1-5, 17, and 33-34 read on the elected species. This election is made without prejudice to or disclaimer of the other claims or inventions disclosed.

This election is made with traverse.

Applicants note that the Examiner's requirement for election of species between the claimed full-length sequence and fragments thereof is unusual. Applicants respectfully submit that the USPTO commonly examines a full-length sequence and fragments thereof together. Further, the Examiner has required an election of species within a species (a generic fragment or a specific fragment). Applicants respectfully submit that this too is contrary to normal USPTO practice.

Applicants respectfully traverse the restriction requirement as it applies to fragments of sequences of Group I and generic fragments of sequences, or any one of the specific

fragments of SEQ ID Nos: 88-102. It is the Examiner's position that each of such species is distinct and the search for each species is not co-extensive. *See* Paper 13, page 2.

However, even where two patentably distinct inventions appear in a single application, restriction remains improper unless the Examiner can show that the search and examination of both groups would entail a "serious burden" (*see* MPEP § 803).

Applicants submit that a search of any one of the above-identified species would provide useful information for each species. In addition, the claimed protein fragments and derivatives, and nucleic acids encoding such proteins fragments and derivatives, have functional activities of the R11-ORF-1 tumor associated antigen. Therefore, a search of any such subset, or a search of a particular functionality i.e., inducing or augmenting an immune response, or treating or preventing cancer, employing R11-ORF-1 tumor associated antigen will necessarily provide useful information for each subset. Therefore the searches are co-extensive and would not impose a "serious burden" for examination together.

Pursuant to M.P.E.P. § 809.02(a), where generic claims are present, the Examiner should identify generic claims or indicate that no generic claims are present and clearly identify each of the disclosed species to which claims are restricted. The Examiner has continued to not taken any such action or provide reasoning for the restriction of the species.

Further, Applicants point out that the Examiner has not addressed MPEP § 803.04, directed to nucleotide sequences. Pursuant to the notice *Examination of Patent Applications Containing Nucleotide Sequences*, 1192 O.G. 68 (November 19, 1996), §803.04 holds that even when nucleotide sequences encoding different proteins are contained in an application, a reasonable number, normally ten sequences, will be examined in a single application. Thus, Applicants respectfully submit that the present requirement for election is improper.

However, even if the Examiner contends that the instant nucleic acids encode different proteins within the scope of §803.04, Applicants submit that a reasonable number of such nucleic acids should be examined together, and the Examiner has given no indication why ten sequences are unreasonable in the present case. Additionally, Applicants note that if an elected species is found allowable, it is proper for the Examiner to examine the next sequence within the same application.

Further, Applicants remind Examiner that the claims of Group I are related to the claims of Groups IV, V, VI, and VII between a product (Group I) and a method for using the product (Groups IV, V, VI, and VII), and further, the method claims comprising Groups IV, V, VI, and VII depend from and include all the limitations of the product claims of Group I. In light of the decisions in *In re Ochiai*, 71 F.3d 1565, 37 USPQ2d 1127 (Fed. Cir. 1995) and *In re Brouwer*, 77 F.3d 422, 37 USPQ 2d 1663 (Fed. Cir. 1996), a notice was published in the Official Gazette which set forth new guidelines for the treatment of product and process claims. *See* 1184 OG 86 (March 26, 1996). Specifically, the notice states that:

> in the case of an elected product claim, rejoinder will be permitted when a product claim is found allowable and the withdrawn process claim depends from or otherwise includes all the limitations of an allowed product claim.

Id. Accordingly, if claims of Group I are found allowable, Applicants respectfully request that the claims of Groups IV, V, VI, and VII be rejoined and examined for patentability. *See also* M.P.E.P. § 821.04.

Reconsideration and withdrawal of the Restriction Requirement, and consideration and allowance of all pending claims, are respectfully requested. It is not believed that

extensions of time are required, beyond those that may otherwise be provided for in accompanying documents.

However, if additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a), and any fees required therefore are hereby authorized to be charged to our Deposit Account No. 19-0036.

Respectfully submitted,

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Date: 9/26/02

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Art Unit 1642

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Re: U.S. Utility Patent Application
Appl. No. 09/631,863; Filed: August 3, 2000
For: **Tumor-Associated Antigen (R11)**
Inventors: Konopitzky *et al.*
Our Ref: 0652.2480001/EKS/CML

Sir:

Transmitted herewith for appropriate action are the following documents:

1. Reply to Restriction Requirement; and
2. One (1) return postcard.

It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier. In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Eric K. Steffe
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EKS/CML:dms
Enclosures
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